Hydra TAVR System Receives CE Mark Approval to Treat Aortic Stenosis

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SMT (Sahajanand Medical Technology Pvt Ltd), the leading medical device company of India, focussed on innovative patient care in cardiovascular segment, today announced that Hydra TAVR device received European CE* Mark approval for the treatment of patients diagnosed with aortic stenosis. This regulatory approval paves the path for SMT to tap into a fast growing $3.8 billion global market.

Hydra aortic valve is a self-expandable nitinol based supra annular aortic system with a mechanism for recapturing of the valve during deployment. This unique property of the device helps in precise placement of the valve and ensures orthotopic deployment. Hydra is available in three sizes; 22mm, 26mm & 30mm and is selected depending upon the diameter of the native annulus from 18mm to 27mm.

Clinical data from the Genesis trial conducted in India and presented at the India Valves Conference 2019 held in Chennai, confirm the system's ability to eliminate significant aortic regurgitation. In another CE clinical study conducted in Europe, the system also demonstrated a strong safety profile on 110 patients enrolled till February 2020.

The benefits of the Hydra Aortic Valve System are enabled by its frame design and repositionable and retrievable delivery system. The non-flared inflow section of the frame and supra-annular valve leaflet design ensures better aortic valvular area in smaller annuli and in valve-in-valve settings. The frame features 3 tentacles or antenna for better anchorage and larger cells (10mm) which give better access for the future coronary interventional procedures if required. The delivery cable is highly flexible and 18 French compatible, and the device can be recaptured, repositioned and retrieved even after 85%-90% of deployment of the valve thereby eliminating to almost zero complications of deployment of TAVR device. The precise orthotopic supra-annular placement, positioning and deployment is facilitated by this unique property of re-capturability of Hydra.

Prof Lars Sondegaard, Principal Investigator of the trial opined that, "Hydra is a novel transcatheter heart valve for treatment of patients with severe aortic stenosis. Features that favor this self-expanding technology with supra-annular position of the leaflet include small size delivery system allowing transfemoral access despite small access vessels, flexible system favoring challenging anatomy such as tortuous anatomy and horizontal aorta, large efficient orifice area of the valve, and low rate of paravalvular leakage and pacemaker. During the trials in Asia, Europe and New Zealand more than 200 patients have benefited from the Hydra valve and I am certain it will fill an important space in the near future."

With a CE certification, SMT looks forward in expanding its structural heart business across Europe. Speaking about the new achievement, the Founder and Chief innovator of Hydra Valve, Mr Swaminathan Jayaraman said, ”The hydra valve has been designed to make the TAVR procedure user friendly and to simplify the procedure with the lowest profile delivery system and a valve where the function of the valve can be observed before the final release. The two set of markers on the Valve is a unique design which provides good visual ability to position the valve and takes the variability out of the difficulties associated with positioning in difficult anatomy.”

SMT has established a regional headquarter in Ireland to better serve its customers in Europe and Middle East. In addition to R&D and manufacturing center in Ireland, SMT has established direct presence and local offices in most of the large markets in Europe. SMT launched Supraflex Cruz DES last year in Europe and got critical success. Now with Hydra, SMT will be able to better serve its customers and patients across Europe.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 75 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of Coronary healthcare. SMT also pioneered the introduction of biodegradable polymer in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

**The CE Mark indicates that the product satisfies requirements of EU Directives (EU : The European Union) and all products need to be CE certified to be sold in Europe.*

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